PSJ3

Exhibit 400

Government & Public Policy Council and Specialty and Biotech Distributors Council Meeting

February 6, 2014

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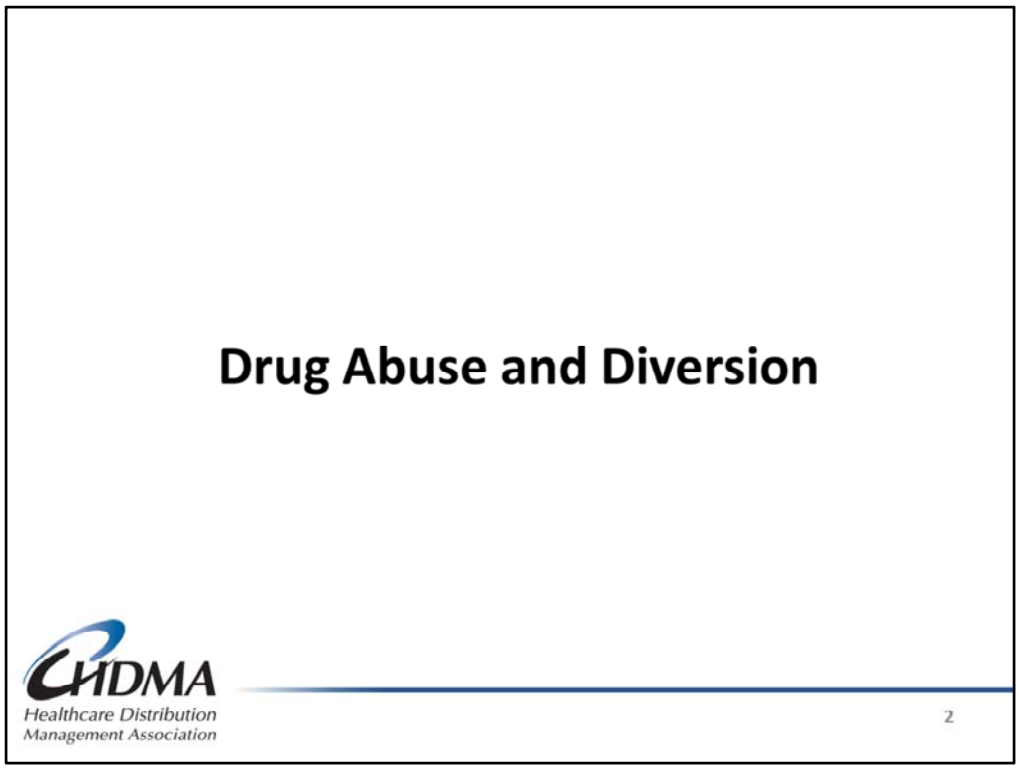
1


Drug Abuse and Diversion
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Federal Legislation

Marino/Blackburn draft

- HDMA supports current draft
- Trying to identify Democrat original co-sponsor
- Potential for House Energy and Commerce activity (hearing/mark-up)
- Senate strategy (Judiciary)

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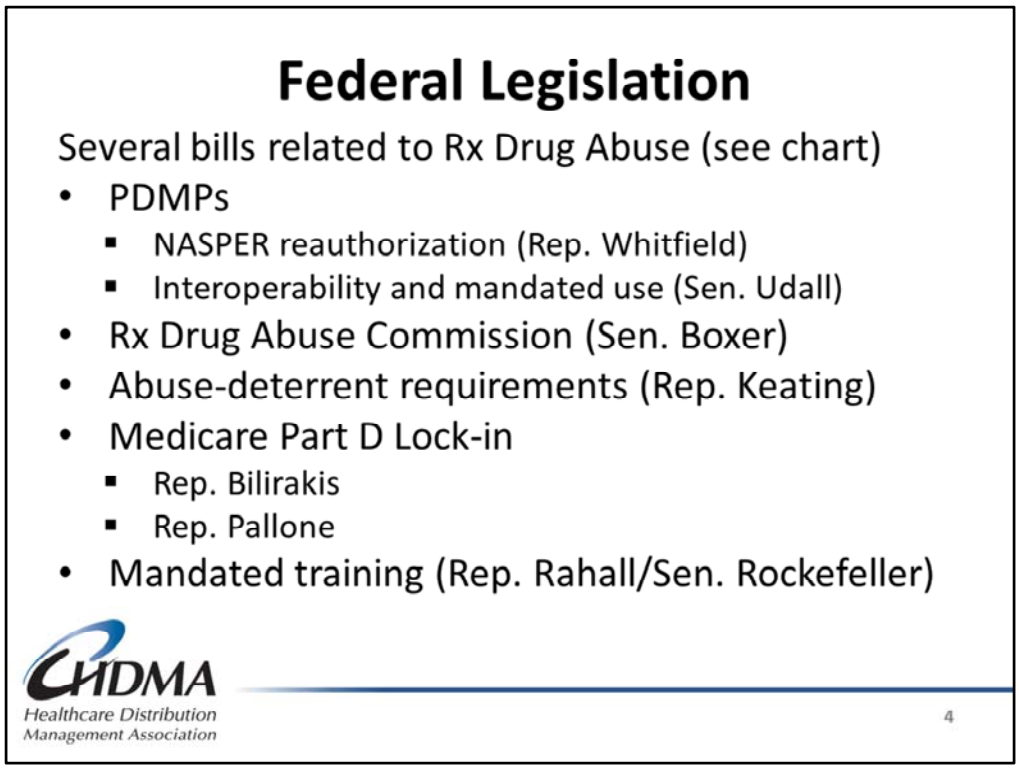
3


Federal Legislation
Several bills related to Rx Drug Abuse (see chart)
PDMPs
NASPER reauthorization (Rep. Whitfield)
Interoperability and mandated use (Sen. Udall)
Rx Drug Abuse Commission (Sen. Boxer)
Abuse-deterrent requirements (Rep. Keating)
Medicare Part D Lock-in
Rep. Bilirakis
Rep. Pallone
Mandated training (Rep. Rahall/Sen. Rockefeller)
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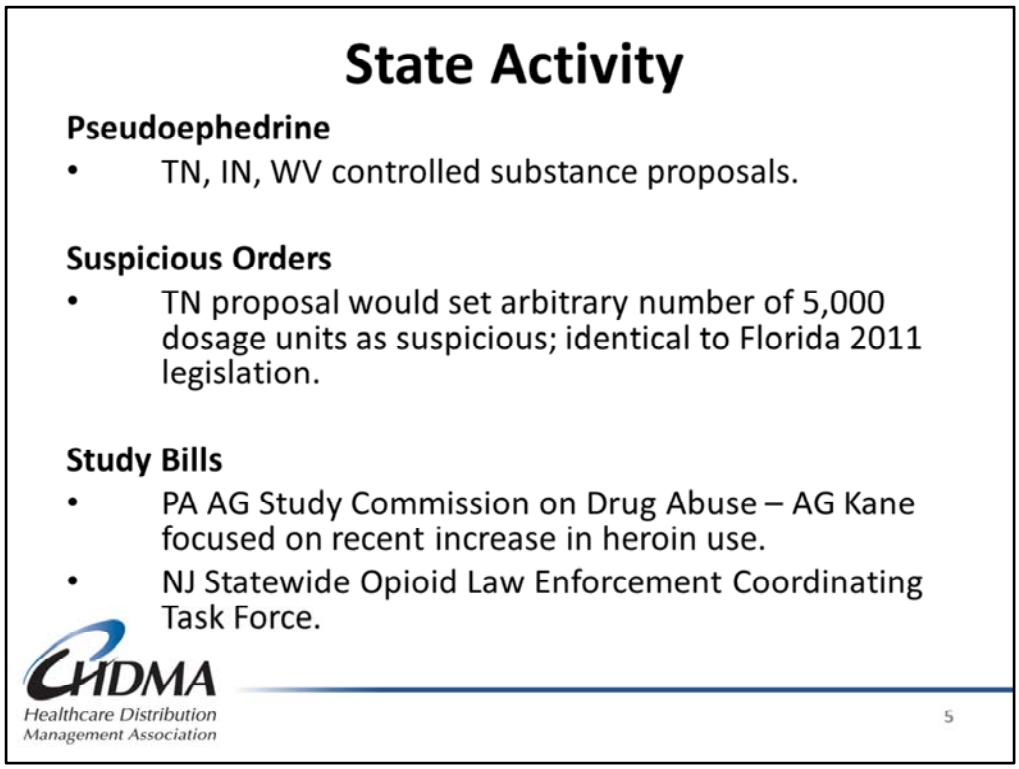
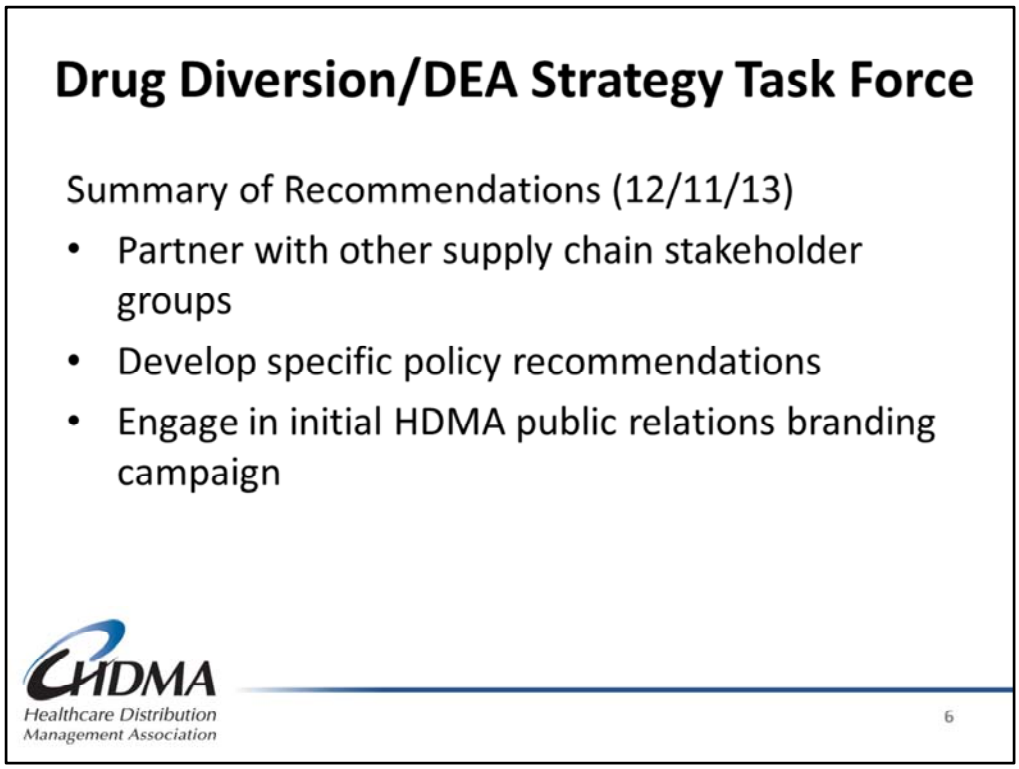


- Just a thought, you don't have to add to the slides but I am seeing a lot of DXM related bills this year.


Drug Diversion/DEA Strategy Task Force
Summary of Recommendations (12/11/13)
• Partner with other supply chain stakeholder groups
• Develop specific policy recommendations
• Engage in initial HDMA public relations branding campaign
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ICG Replacement Statement

- GPPC guidance at last meeting:
  - "Take down" ICG (done)
  - Create a "Replacement Statement"
- Initiated statement development under the RAC, but did not complete (sensitivities)
- Asked RAC's opinion on using: "*Primary Pharmaceutical Distributors are Committed to the Prevention of Prescription Drug Abuse and Diversion*"
  - One requested further review.

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Question for GPPC – How Should HDMA Approach the "Replacement Statement"

- **Option 1:** Rely on the new policy statement "*Primary Pharmaceutical Distributors Are Committed To the Prevention of Prescription Drug Abuse and Diversion*"?
  - HDMA recommended
  - Upon follow-up, key RAC members agree
  - A different statement unlikely to help
- **Option 2:** Create a separate statement as originally directed.
  - Difference – could be more compliance focused

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Alliance to Prevent the Abuse of Medicines (APAM)

The mission of the Alliance is to raise awareness of the issue of prescription drug abuse, partner with legislators to craft achievable solutions, and serve as a resource for policymakers and the media.

Current Members of the Alliance:

- American Medical Association
- Cardinal Health
- CVS Caremark
- Healthcare Distribution Management Association
- Prime Therapeutics
- Teva Pharmaceuticals

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NGA Prescription Drug Report

Reducing Prescription Drug Abuse: Lessons learned from an NGA Policy Academy. Report chronicles state* efforts to address/mitigate Rx abuse.

Primary findings:

- Leadership matters
- Prescribing behavior needs to change
- Disposal options need to be convenient/cost effective
- PDMPs are underutilized
- Public education is critical
- Treatment is essential
- Data, metrics, and evaluation must drive policy and practice

(*) States participating: Alabama, Colorado, Arkansas, Kentucky, New Mexico, Oregon and Virginia

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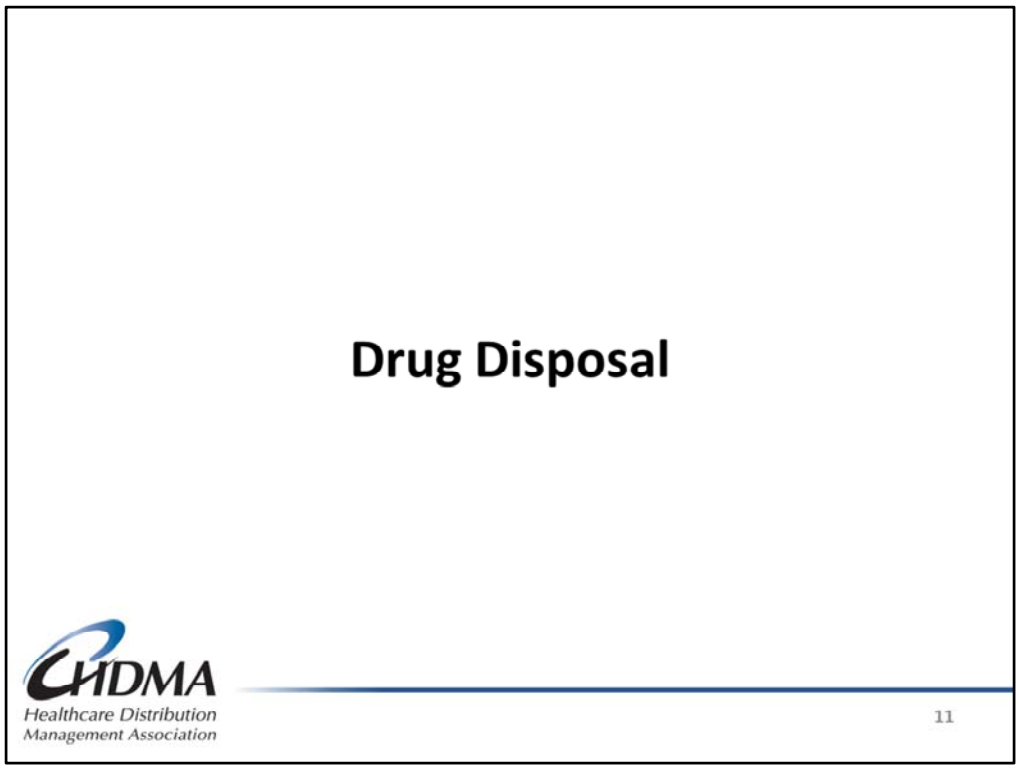
10


Drug Disposal
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DEA Disposal/Take Back Rule

- Proposed – 12/12; HDMA comments 2/13
- Significant issues; federal/state EPA conflicts
- Still awaiting final rule
- GPPC guidance at last meeting:
  - Joint letter to ONDCP ***IF*** adequate number of participants/buy-in
  - Possible OMB meeting
- Not achievable - inadequate "buy-in"

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HDMA - EPA Meeting Agenda - 1/7/14

- Gave distribution overview (including returns)
- EPA involvement in DEA rule
- Discussed anticipated EPA proposal on pharmaceutical waste (~ Aug. 14)
- Key "take away": EPA "*reevaluating*" current policy; may consider returns for credit as "waste"
  - Unclear whether/how affects distributors
  - Potential for significant impact
  - EPA says: some states pressing for this, b/c a return for credit is still "waste"

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Potential Impact If Unsaleable Returns are "Waste"

- Reverse distributors - might not be allowed to accept certain returns
- Forward distributors - may be subject to federal/ state environmental regs, e.g., face requirements to
  - Assess outgoing returns; separate if hazardous waste (HW)
  - HW tracking and reporting requirements
  - Time limits on product held on site
  - Obtain EPA Identification Number (type of licensure)
  - Much more
- NACDS separately met with EPA; wants status quo

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Discussed with RAC and SGAC

- RAC
  - Concerned about potentially significant impact
  - Little we can do/recommend without seeing the proposed rule
- HDMA asked SGAC
  - Should we find out which states are pressing federal EPA?
  - Should we discuss impacts with BOPs; ask if they would intervene with state environmental staff?
- SGAC evaluating this idea internally within their companies

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Question for GPPC

Should HDMA take further measures (federal)? e.g., request a meeting with 'higher level" at EPA or OMB

- Can't evaluate impact without seeing the rule
- EPA unlikely to say/do anything other than tell us to comment on proposed rule
- HDMA does not recommend this step, *but* wishes to hear GPPC feedback

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State/Local Activity

- Alameda County, CA is still on appeal to the U.S. Court of Appeals for the 9th Circuit after the U.S. District Court for the Northern District of California rejected the manufacturers' arguments.
- Monitoring other local jurisdictions and states for similar proposals.

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17


Pedigree/Traceability Implementation
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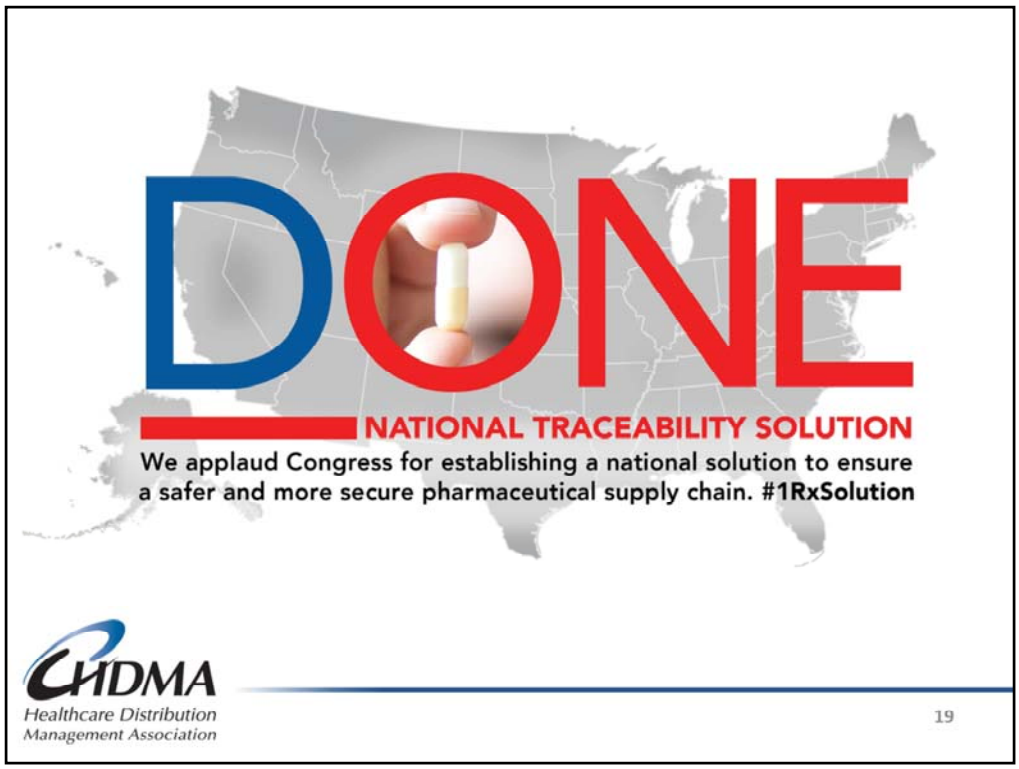
DONE
NATIONAL TRACEABILITY SOLUTION
We applaud Congress for establishing a national solution to ensure a safer and more secure pharmaceutical supply chain. #1RxSolution
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Implementation

- HDMA Staff Implementation team organized by subject matter and issues
- Traceability Implementation Work Group
  - Member work group of key individuals from member companies, mostly those who participated in CA and Federal Pedigree Work Groups
  - Cross section of Operations, Regulatory, IT, Compliance and Government Affairs
  - 3 in-person meetings & weekly calls since 11/27
- Active participation in PDSA
- Identification of priorities and strategy development
- Working with other stakeholder groups on specific areas, e.g., Licensure, Information/data exchange, etc.

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Implementation – Key Issues

- Suspect/illegitimate product (FDA Guidance - 5/26)
- Data exchange requirements (TI/TH/TS) & compliance options for various process flows / product movement scenarios (FDA Standards - 11/27)
  - HDMA technical groups to revise ASN & invoice standards, work with GS1, etc.
- Preemption review and State outreach / education (ongoing)
  - Pedigree & Licensure
- Open dialogue with other stakeholders, Hill staff, FDA where appropriate
  - Upcoming FDA Meeting – Distribution 101 (2/10)

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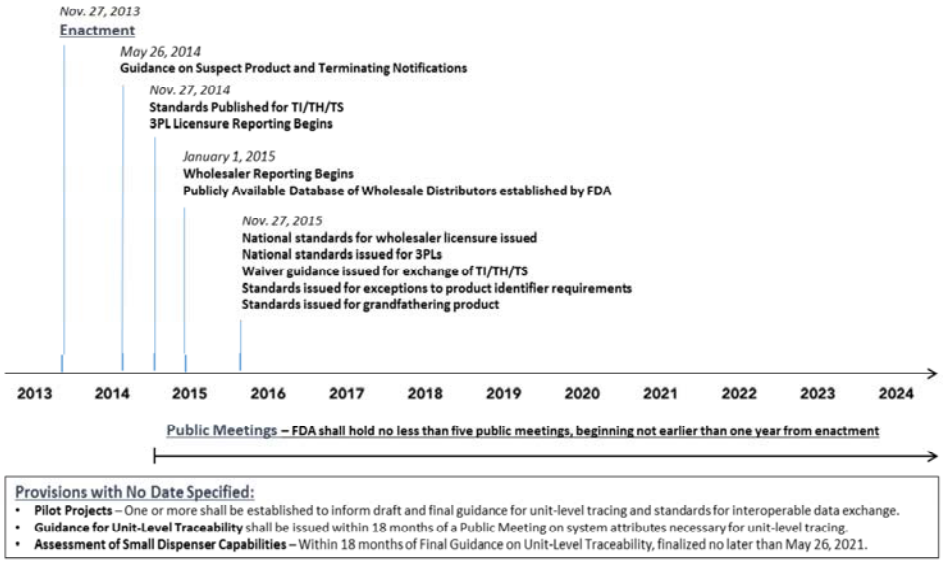
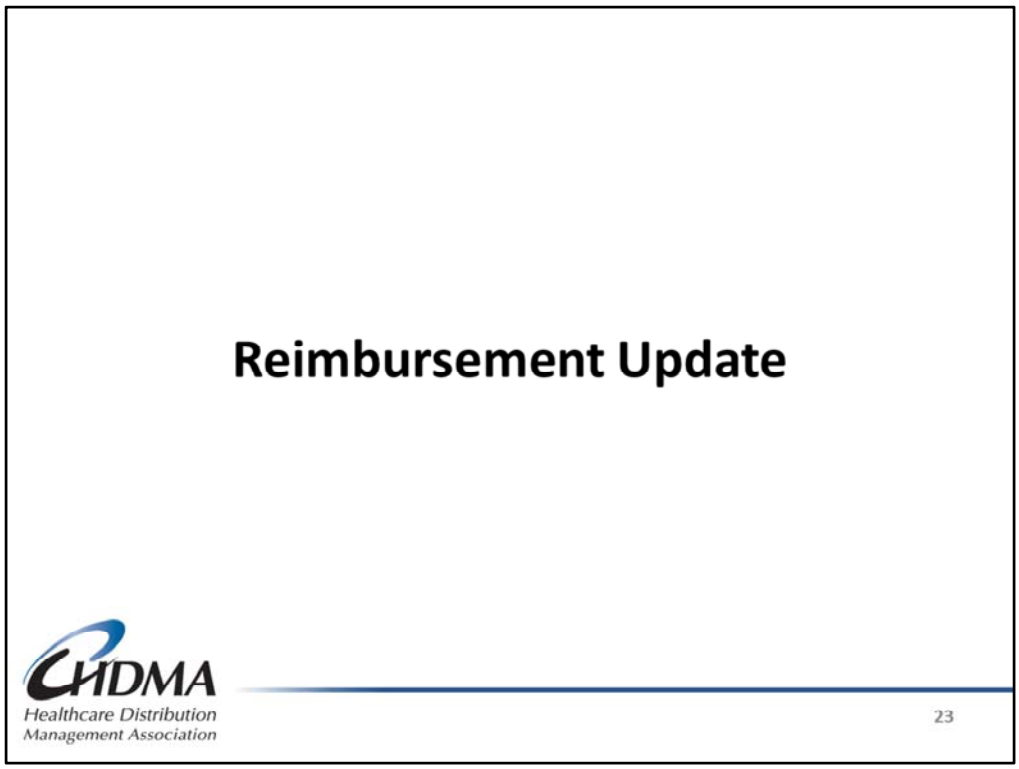
21

FDA Implementation Timeline



Provisions with No Date Specified:

- **Pilot Projects** – One or more shall be established to inform draft and final guidance for unit-level tracing and standards for interoperable data exchange.
- **Guidance for Unit-Level Traceability** shall be issued within 18 months of a Public Meeting on system attributes necessary for unit-level tracing.
- **Assessment of Small Dispenser Capabilities** – Within 18 months of Final Guidance on Unit-Level Traceability, finalized no later than May 26, 2021.


Reimbursement Update
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CMS Rule on Medicare Parts C & D

On January 10 CMS issued a proposed rule detailing significant change to the Medicare Part C & D Programs.

Notable proposed changes:

- Provisions to require physicians to enroll in Part D to better monitor excessive/abusive prescribing practices
- Mandate that drug pricing standards be updated at least every 7 days
- Supports medication therapy management (MTM) programs

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CMS Finalizes NADAC

The agency finalized **National Average Drug Acquisition Cost (NADAC)** Files on November 27, 2013. Will update files weekly. Does not include specialty pharmacies nor does it include off-invoice discounts.

- States must file SPAs with CMS to transition to NADAC for Medicaid (AL, CO, ID, IA, LA and OR already using acquisition cost as Medicaid reimbursement metric)
- Private payors may begin to reference NADACs as they are final and publicly available.

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GAO Report on FULs

On January 22 the Government Accountability Office Released a report titled "*Medicaid Prescription Drugs: CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Cost*"

GAO Recommendations:

- Expeditiously implement the PPACA-based FUL formula to better control federal reimbursement for Medicaid covered outpatient prescription drugs.
- Monitor the relationship between PPACA-based FULs and the NADACs on an ongoing basis to help determine whether PPACA-based FULs effectively control federal Medicaid expenditures without reducing beneficiary access to drugs subject to FULs over time.

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Final AMP Rule?

According to a timeline published by HHS/CMS, we still expect the final AMP rule to be published no sooner than May, 2014.

In another communication dated November 27, CMS indicated that the agency will finalize AMP based FULs in July, 2014.

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ASP/Prompt Pay

Prompt pay

- SGR Reform (9-month patch vs. long-term)

ASP

- Pay-for risk
  - SGR
  - Debt ceiling

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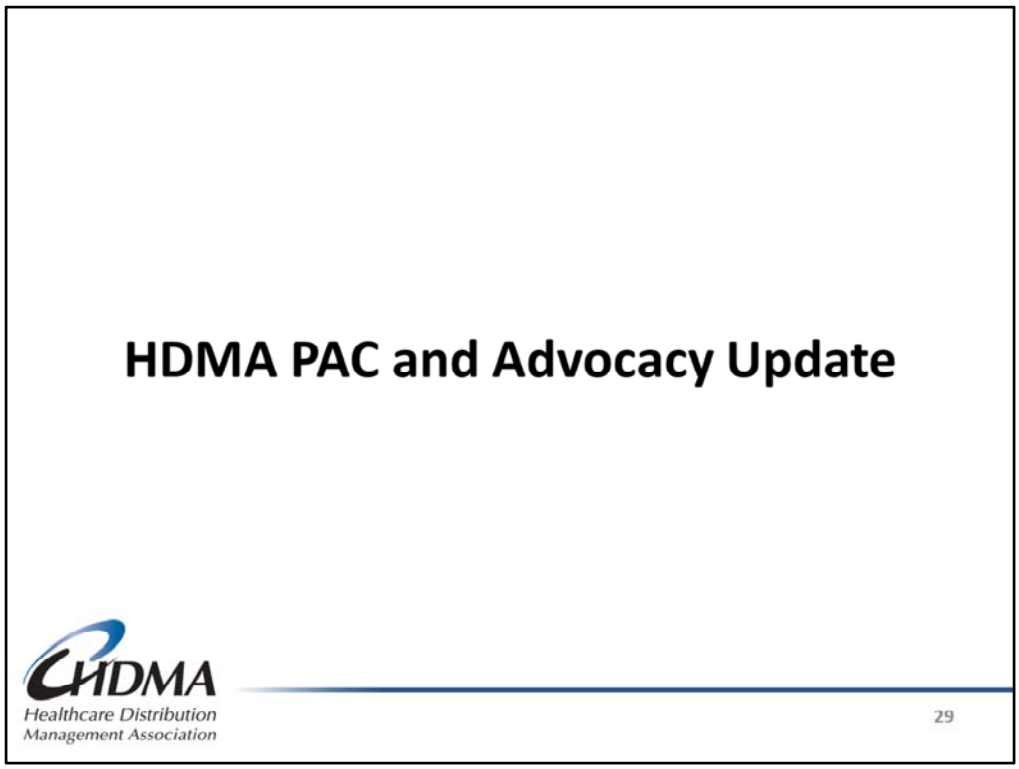
28


HDMA PAC and Advocacy Update
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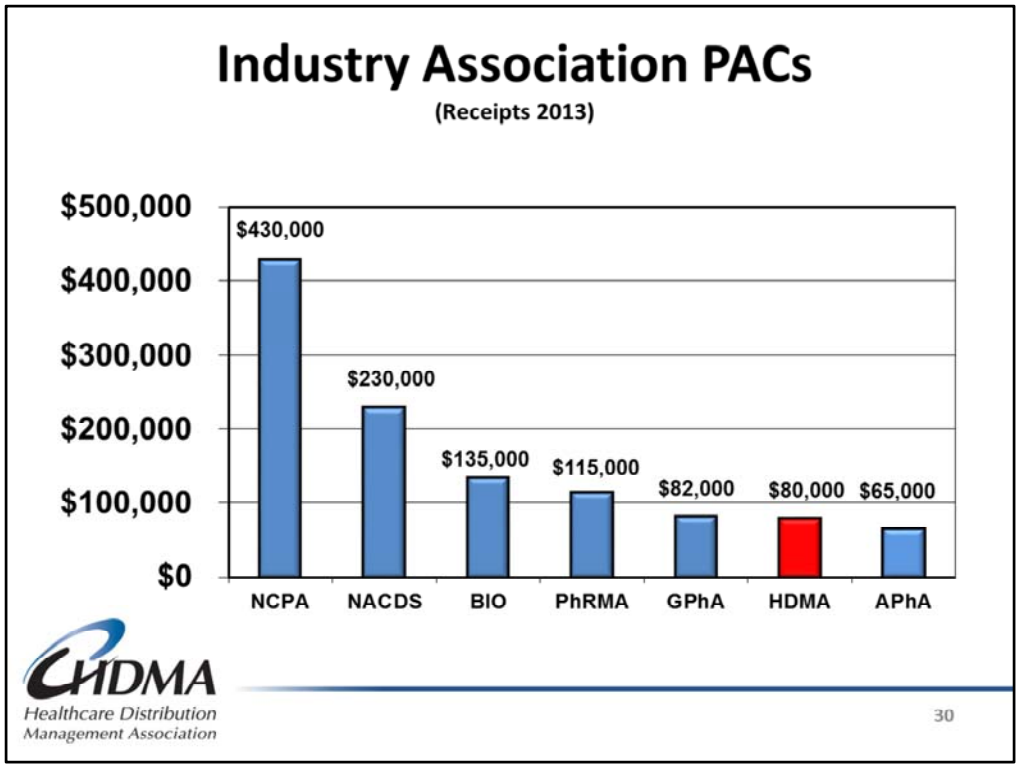
Industry Association PACs
(Receipts 2013)
$500,000
$400,000
$300,000
$200,000
$100,000
$0
$430,000
$230,000
$135,000
$115,000
$82,000
$80,000
$65,000
NCPA
NACDS
BIO
PhRMA
GPhA
HDMA
APhA
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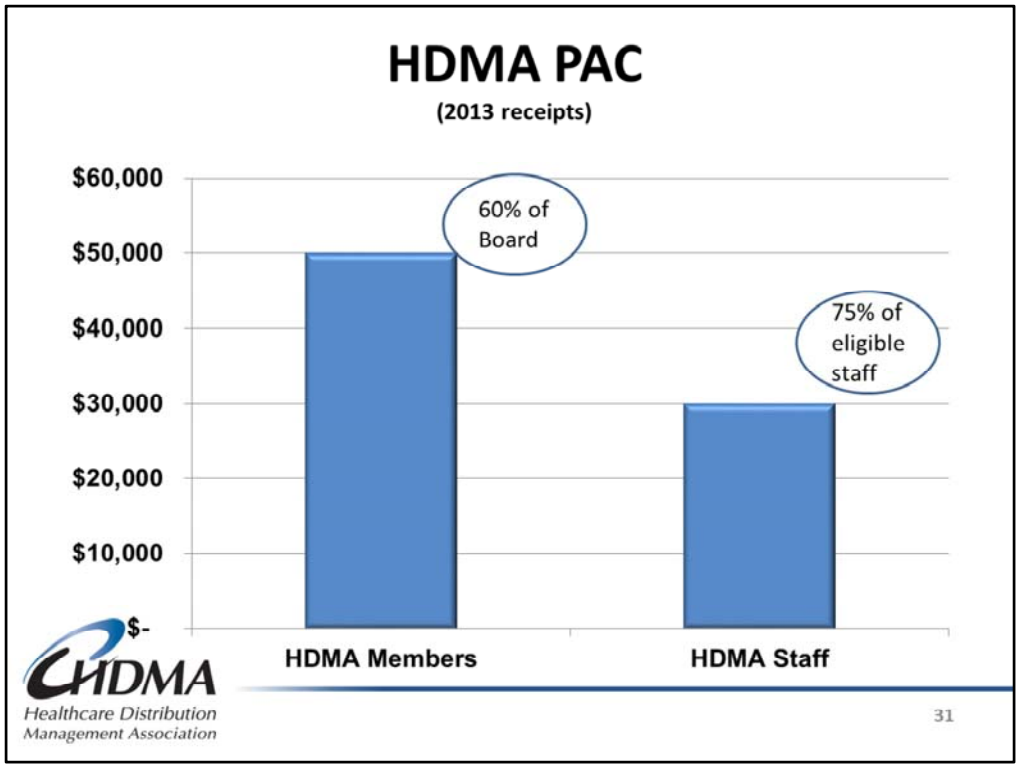
30


HDMA PAC
(2013 receipts)
$60,000
$50,000
$40,000
$30,000
$20,000
$10,000
$-
60% of Board
75% of eligible staff
HDMA Members
HDMA Staff
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31


2014 DISTRIBUTION CENTER CHALLENGE
CHDMA
Be a Voice for the Distribution Industry
Join the Distribution Center Challenge | Meet with your legislator in D.C. or at home | Participate in HDMA Hill Day
Click here for more information about getting involved with HDMA advocacy activities and the Distribution Center Challenge.
For questions, contact Jewelyn Cosgrove, Associate Director, Federal Government Affairs, at (703) 885-0272.
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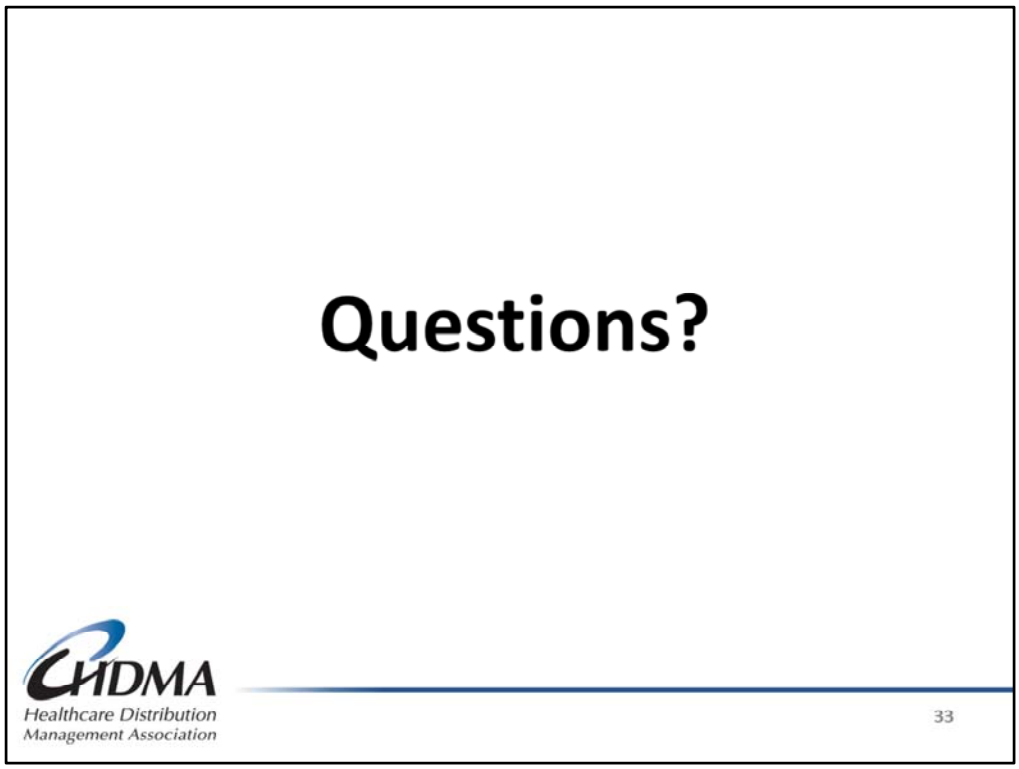
Questions?
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